K012992 1/2

OCT - 2 2001

Premarket Notification
510(k) Summary
CoolTouch "VariZoom"
Variable Spot Size
Reusable Fiber Optic Handpiece

This 510(K) Summary of safety and effectiveness for the CoolTouch "VariZoom" variable spot size reusable fiber optic handpiece is submitted in accordance with the requirements of 21 CFR 807.92.

Applicant:	CoolTouch Corporation
Address:	9085 Foothills Boulevard Roseville, CA 95747
Contact Person:	Donald V. Johnson
Telephone:	(916) 677-1900
Fax:	(916) 677-1901
Preparation Date:	September 4, 2001
Device Trade Name:	CoolTouch "VariZoom"
Common Name:	Laser Fiber Optic Delivery System Handpiece
Classification Name:	Accessory to Laser Surgical Instruments 79-GEX
Legally Marketed Predicate Device:	The predicate device is the CoolTouch Corporation Model CoolTouch "Varia" Nd:YAG Laser System, 510(k) # K983984, July 7, 1999. The beam delivery system was described in the 510(k); the cooling handpiece was also described in detail as an accessory in the Operator Manual.
Description of the CoolTouch Corporation VariZoom handpiece:	The fiber optic handpiece used with the CoolTouch Varia laser system has had a fixed spot size. The user selects a 4mm, 6mm, or 8mm spot size, depending on the application. The VariZoom handpiece combines the various spot size handpieces into one, allowing the user to dial the desired spot size instead of changing handpieces. The VariZoom handpiece has the same coolant capability and incorporates a sensor to alert the user that the coolant is depleted.

The following table describes the CoolTouch "Varia" fixed spot size handpieces and compares them to the CoolTouch "VariZoom" variable spot size handpiece.

Technical Specification Comparison

Specification	CoolTouch "Varia" Fixed Spot Size Fiber Optic Handpiece	CoolTouch "VariZoom" Variable Spot Size Fiber Optic Handpiece
Wavelength	1064 nm	Same
Dimensions	20cm x 5cm x 10cm (LxDxH)	Same
Weight	2 lbs.	Same
Cooling	Dynamic cooling using a solenoid valve and self-contained coolant	Same
Compatibility	CoolTouch Varia Nd:YAG Laser System	Same
Laser Spot Size	4, 6, 8mm	Variable, 3mm to 10mm
Indications	Numerous	Same
510k Number	K983984 K003781 K010316	Pending

Intended use of the CootTouch Corporation VariZoom handpiece:	The intended use of the VariZoom handpiece is the **same intended use** as previously cleared for the CoolTouch "Varia" Nd:YAG Laser System per 510(k) #K010316.
Nonclinical Performance Data:	None.
Clinical Performance Data:	None.
Conclusion:	The CoolTouch VariZoom handpiece described in this submission is substantially equivalent to the predicate CoolTouch 4, 6, and 8mm spot size handpieces.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2001

Mr. Donald V. Johnson
Vice President of Operations
New Star Lasers, Inc.
9085 Foothills Boulevard
Roseville, California 95747

Re: K012982
Trade/Device Name: CoolTouch VariZoom
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 5, 2001
Received: September 5, 2001

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MD

for – Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number ~~Pending~~ K012982

Device Name CoolTouch VariZoom Variable Spot Size Reusable Fiber Optic Handpiece

Indications for Use The CoolTouch VariZoom Variable Spot Size Reusable Fiber Optic Handpiece is indicated as an accessory for use with the CoolTouch "Varia" Nd:YAG Laser System, which has been cleared for the following indications:

Hair removal (destruction of hair follicles) in all skin types and for soft tissue applications. For coagulation and hemostasis of vascular lesions. For pigmented lesions to reduce lesion size, for patients that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012982